# More guidelines on research ethics?

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With its new research ethics guidelines, the UK Royal College of Physicians continues a useful tradition of providing guidance to medical researchers.

Does the average member of a research ethics committee (REC) or the average researcher really need yet more guidance? In the UK, the Department of Health, the National Research Ethics Service, the Medical Research Council, the Association of the British Pharmaceutical Industry, the General Medical Council, a number of medical Royal Colleges and a variety of other professional groups seem to be falling over each other in their enthusiasm to indicate how ethical review should be organised, considered or determined. Other countries may have less guidance, but in the UK there seems to be a surfeit of opinion and advice. Surely no more is needed.

Against this background, the UK's senior professional medical body, the Royal College of Physicians (RCP) in London has just launched more guidance: the fourth edition of its *Guidelines on the practice of ethics committees in medical research with human participants*[1] (hereafter called "the *Guidelines*"). With the lapse of more than 10 years since the last edition, some might wonder whether it isn't time for the RCP to disengage from the increasingly regulated environment of ethical review of research. Why should the average REC member, the average investigator or those involved in research governance rush to obtain a copy of yet another publication?

The need for this document was debated well before the enterprise of producing it was begun. It was clear that any new document would require almost the entire rewriting of what had been produced previously—a job not lightly undertaken. The challenge was to produce a document that—along with the Department of Health's *Governance arrangements for NHS research ethics committees*[2] (GAfREC)—provides the REC member with the essential equipment to do the job of research ethics review and the intending investigator with the guide to think ahead about the ethics of the planned project. In addition to practical guidance, there was also a perceived need for direction to the invaluable materials that have been published by many other bodies reporting from more limited perspectives. The more general statements of the Declaration of Helsinki[3] are too unfocused for many practical situations where the details are often critical. Some may believe such ambitions unrealistic and the abundance of more discrete packages of guidance on the web a better approach. Against this, the RCP would argue that there are advantages to a book that is ready to hand, provided its contents are accessible.

Professionals often overlook the needs of those who are not familiar with their field. Those who work in the health service forget that the jargon-filled world of the healthcare professional is not understood by those coming in from the outside to sit around the REC table. Even insiders often lack both a crucial knowledge and a critical understanding of essential organisation, terminology and processes, as well as of the structures of research itself. A first requirement might therefore be to set ethical review in its context—particularly a European one—and to supplement the organisational directives of GAfREC. The international aspect is growing in importance. Pharmaceutical trials, in particular, are frequently multinational, yet subjected to varying processes of ethical review. Organisations such as the European Forum for Good Clinical Practice or the Council of Europe expend considerable effort in trying to promote discussion and common practices. Some acknowledgement that ethical review extends beyond the national frontier is surely appropriate. The assumption that ethical review is best in the UK reflects an outdated arrogance. These are themes that could be expanded in future editions of this or other guidance.

The first task of REC members is to understand the protocol in front of them. Without that understanding, an ethical opinion is incompetent. What, for example, is a patient preference trial or an equivalence trial, a placebo run-in or an open label extension? And following from that, what might the ethical implications be? The *Guidelines* describe the varieties of medical research, both observational (including qualitative) and experimental, outline the issues arising from audit and offer a glossary that will guide the uninitiated through some of the basics. These aspects of the document are genuinely new in any comprehensive guidance. The difficulty with any simple taxonomy of this sort is one of oversimplification. Does qualitative research sit comfortably, for example, as just another variety of observational study? There is a trade-off between accuracy and understanding. It is inevitable, too, that the main emphasis is on medical rather than social research, even if the latter is accommodated at various points.

The work of ethical review is not primarily about the law. Yet the REC member or investigator should have some background understanding of legal issues—the basic ones arising from the European Community Clinical Trials Directive,[4] which has so greatly influenced current practice even for non-pharmaceutical studies, the Mental Capacity Act, the Human Tissue Act and the legal background to issues of consent, confidentiality, data protection and indemnity. In the writing of the document, a comprehensive exposition of the law was impossible. An attempt has been made to select those issues that arise most commonly, and there is acknowledgement of the Scottish aspect. Similarly, an understanding of ethical principles and how they apply to research is needed. The *Guidelines* have adopted a simplified account with a series of linear decisions, commencing with validity; proceeding to welfare, which is protected by considerations of either professional equipoise/uncertainty or minimal risk; and ending with consent. The latter is, of course, neither sufficient nor, on occasions, even necessary to make research ethical.[5] Nevertheless, consent is crucial in many studies, and guidance is needed. This covers, for example, when consent can be dispensed with, when it might follow rather than precede randomisation, how it can be obtained when there are sensory or language difficulties, when a proxy can give it, how to proceed when a cluster rather than an individual is randomised and what to do when deception is to be part of the research design.

The *Guidelines* do not offer an agreed position on ethical theory. This may be disappointing to some: so much guidance seems to short-change the reader on the basic principles. Even at the next level, there was disagreement within the RCP's working group itself on how or whether the term *equipoise*, for example, should be used. The priority was seen as introducing a practical scheme to guide the uncertain through the relevant territory, with direction to where further help can be sought

if needed. It seems surprising that quite radical differences of opinion on meta-ethical foundations often don't seem to lead to such widely separated views on final decisions. Perhaps guideline writers are wise to avoid theory and adopt a ''normative'' approach.

Research on children, prisoners, the dying, the mentally incapacitated and refugees creates particular concerns. Similarly, particular varieties of research such as those involving special procedures (notably surgery), complementary therapies, medical devices or genetics generate specific questions. So does money—a source of some research fraud and a thorny issue for many committees, which they are charged to address by guidelines for good clinical practice.[6] These are the detailed areas where, it is hoped, a key sentence or two could at least raise the questions that need to be addressed.

Professional bodies have freedoms beyond those of government agencies or regulatory bodies. This allows the expression of opinion and the advocacy of change. Even the act of writing about research at the end of life or among refugees, for example, points out the great need for work in these areas. The RCP has also advocated a strong position on the moral importance of ethical research[7]: the exact phrasing of this was one of the most contentious issues in the working group. In a memorable paper, Harris contended that ''*biomedical research involving human subjects cannot legitimately be neglected and is therefore both permissible and mandatory, where the importance of the objective is great and the possibility of exploitation of fully informed and consenting subjects is small.*''[8] The final version from the RCP replaced ''mandatory'' with ''recommended''—the sort of compromise that so easily reduces the force of what is being advocated and is, one reflects, the hallmark of committees. The importance of clinical trial registration is similarly given strong emphasis as a condition of ethical approval. But there are other areas where firm views have been expressed: for example, ''the greatest burden of disease in the developed world falls upon older people and research activity should reflect this''; or, more controversially, perhaps, on sham surgery (''an absolute prohibition on its use seems unwise''); or on whether a prisoner representative is needed on those RECs considering research in prisons (this ''could be considered in future developments''). All of these raise controversies that a body such as the National Research Ethics Service would avoid. So perhaps the view of a professional body does still have a distinct voice.

It is a fact of the historical record that, along with the Medical Research Council, no professional body has played a greater role in the development of ethical review in the UK than the RCP. It originally proposed RECs in its Rosenheim Report in 1967,[9] subsequently established their structures with the support of the Department of Health and Social Security[10] and went on to produce the first guidelines in 1984. The College's latest document continues a progressive liberal tradition and tries to provide an accessible tool for quick reference or armchair browsing, not just for those in the UK but for those elsewhere who seek an overview of the practice of research ethics. If through its *Guidelines* the RCP has provided a comprehensive, accessible yet concise set of ethical advice to researchers, conveyed a belief in the moral value of good research and succeeded in articulating a progressive position to advocate, then one more set of guidelines will have been justified.

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